NOV 2 6 2013

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Section 5 - 510(k) Summary

1. **Submission Sponsor**

Mega Electronics Ltd
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2. **Submission Correspondent**

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Contact: André Kindsvater, Senior Consultant, QA/RA
Email: project.management@emergogroup.com

3. **Date Prepared**

May 20th, 2013

4. **Device Identification**

Trade/Proprietary Name:	eMotion ECG Mobile
Common/Usual Name:	Digital Ambulatory Monitor
Classification Name:	Transmitters And Receivers, Electrocardiograph, Telephone
Classification Regulation:	21 CFR 870.2920
Product Code:	DXH
Device Class:	Class II
Classification Panel:	Cardiovascular

5. **Predicate Devices**

Heartrak Smart ECAT, 510(k) Number: K083535
Card Guard PMP4 Medical Web Center, 510(k) Number: K050940

6. Device Description

The eMotion ECG Mobile is a mobile device, PC and Internet based telemetry solution for the ambulant monitoring of the plug-in device data of chronic patients via a mobile network. Plug-in devices can be ECG devices, blood pressure monitors, weighing scales, etc. The device reads data from the plug-in device via a Bluetooth connection. The application in the mobile device sends the data to a server (Health Gateway) over mobile networks using the secured connection.
Data can be viewed from the Health Gateway server using the Web Monitor. Monitoring is performed using PC application that reads data from the server over the internet using the secured connection.

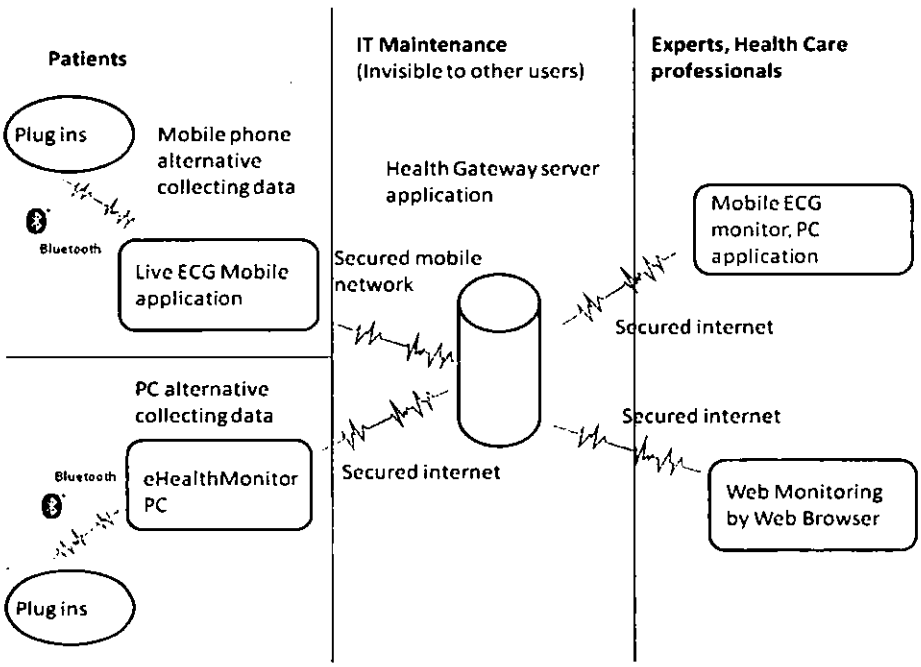

Figure 5-1. eMotion ECG Mobile concept

7. Intended Use

The eMotion ECG sensor is a wearable, portable, externally applied, electrocardiograph recorder and transmitter for the purpose of health monitoring, biofeedback and scientific research.

The eMotion ECG Mobile is intended for use in clinical and non-clinical settings to collect and transmit health parameters to healthcare professionals for monitoring and evaluation.
Health parameters are collected from a variety of commercially available, external plug-in devices such as ECG sensors, Weight Scales, Blood Pressure Meters and Pulse Oximeters.

The eMotion ECG Mobile does not provide any automatic analysis or diagnosis.

8. Comparison of Technological Characteristics

The following table compares the eMotion ECG Mobile to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**Mega Electronics Ltd**	**Universal Medical Inc.**	**CARD GUARD SCIENTIFIC SURVIVAL, LTD**
Trade Name	eMotion ECG	Heartrak Smart ECAT	Card Guard PMP4 Medical Web Center
510(k) Number	TBD	K083535	K050940
Product Code	DXH	DXH	DXH
Regulation Number	21 CFR 870.2920	21 CFR 870.2920	21 CFR 870.2920
Regulation Name	Transmitters And Receivers, Electrocardiograph, Telephone	Transmitters And Receivers, Electrocardiograph, Telephone	Transmitters And Receivers, Electrocardiograph, Telephone
Indications for Use	The eMotion ECG sensor is a wearable, portable, externally applied, electrocardiograph recorder and transmitter for the purpose of health monitoring, biofeedback and scientific research. The eMotion ECG Mobile is intended for use in clinical and non-clinical settings to collect and transmit health parameters to healthcare professionals for monitoring and evaluation. Health parameters are collected from a variety of commercially available, external plug-in devices such as ECG sensors, Weight Scales, Blood	Heartrak Smart ECAT is a wireless ambulatory, multi-channel, continuous ECG event recorder with embedded arrhythmia detection algorithms. Heartrak Smart ECAT registers symptomatic and asymptomatic cardiac event triggered by a patient manually or auto-triggered by embedded arrhythmia detection algorithms. Using wireless technology, Heartrak Smart ECAT, when placed with range of a compatible RF receiver, uploads recorded ECG parameter data to receiver. When data upload is complete	The PMP4 Medical Web Center is a Software application intended for supporting remote monitoring of Electrocardiographic (ECG), Spirometric, Fetal/Maternal, Blood Pressure, Heart Rate, Blood Glucose, Blood Oxygen Saturation, Body Weight and optionally other patients' vital signs and parameters. The data is received from transducers/monitors, which are external to the system.

Manufacturer	Mega Electronics Ltd	Universal Medical Inc.	CARD GUARD SCIENTIFIC SURVIVAL, LTD
Trade Name	eMotion ECG	Heartrak Smart ECAT	Card Guard PMP4 Medical Web Center
	Pressure Meters and Pulse Oximeters. The eMotion ECG Mobile does not provide any automatic analysis or diagnosis.	data can be reviewed and analyzed at a physician's office, clinic or monitoring center.	
Overall Design	PEMS and Software	PEMS	Software
Sterile	non-sterile	non-sterile	N/A
Single-Use	no	no	No
Battery Operated	Re-chargeable 3.7 V Li-ion battery	Internal Li-Ion rechargeable battery 3.6V	N/A
Data Transmission	Bluetooth & Mobile Net	Bluetooth & Mobile Net	N/A
Sampling rate	Selectable 100, 125, 250, 500 or 1000 Hz	205 Hz	N/A
AC Powered	no	no	N/A
Patient Cable	3-lead	3-lead	N/A
Latex Free	yes	yes	N/A
Data transmission	via mobile device	RF within 10 m	via PDA, Cellular Phone, iTV, PC
Web-based Medical Center Platform	Yes	N/A	Yes
Complies with ISO 10993-1	Yes	Yes	N/A
Electrical Safety Testing Passed	Yes	Yes	N/A

9. Non-Clinical Performance Data

The eMotion ECG Mobile has been fully verified and validated following written test protocols to demonstrate that the design meets the requirements and performs as intended. The test results including pass/fail determination are documented in the corresponding test reports.

The device was also tested against the recognized consensus standard EN 60601-2-25:1999 Basic Safety and Essential Performance of Electrocardiographs.

The proper functioning of the applicable plug in devices was also verified.

The device and the applicable plug-in's passed all tests successfully.

All required software testing was completed as part of the software verification and validation. Please refer to Section 016 Software.

Summary of Performance Testing Result

All the specified performance tests have been passed successfully.

Table 5B – Performance Testing Summary - ECG Sensor

Test		Pass / fail criteria	Results
1	System A/D Conversion	14 bit	Passed
2	Sampling rate	1000 Hz	Passed
3	IP Class	IP20	Passed
4	Signal frequency band	ECG: 1 Hz ... 30 Hz	Passed
5	System sensitivity	1µV / bit (peak to peak) or 0.2µV / bit (peak to peak) switchable ECG: 1.33 µV / bit (peak to peak)	Passed
6	System noise	1 µV RMS	Passed
7	CMRR	90 dB minimum 104 dB typical (type tested)	Passed
8	Signal range	14 bit: +/- 8192µV (peak to peak)	Passed
9	Accelerometer	10-bit +/- 8g mode, typical sensitivity 64 bits/g Output data rate: 250 Hz Accuracy: +/- 5% at 1g	Passed
10	ECG Waveform shape	ECG Complex - Recognizable Ventricular Fibrillation - Recognizable 30, 60, 120, 180 and 240 BPM +/- 2 % Sine wave 10Hz and 40 Hz - +/- 2 %, shape a clear sine wave	Passed
11	Sensor power	Re-chargeable Li-Po or Li-ion 140mAh, 3.7V	Passed
12	Battery life	300 full re-charge cycles (80%)	Passed
13	Operating time	Online with Bluetooth: ca. 4h	Passed

The performance of the commercial OTS plug-ins has been tested and all tests passed successfully.

Table 5C – Performance Testing - OTS Plug-ins

K-Number	Device	Results
K043217	UA-767PBT Digital Blood Pressure Monitor	Passed
K061822	HEM-780N3 Automatic Blood Pressure Monitor	Passed
K102350	3150 WristOX2	Passed
none	UC-321 PBT C40 Weight Scale	Passed
none	HBF-206IT Weight Scale	Passed

The eMotion ECG Mobile meets all the requirements for overall design, biocompatibility, and electrical safety confirms that the output meets the design inputs and specifications. The eMotion ECG Mobile passed all testing and supports the claims of substantial equivalence and safe operation.

The eMotion ECG Mobile complies with the applicable voluntary standards for biocompatibility. The device passed all the testing in accordance with national and international standards.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the eMotion ECG Mobile and the predicate devices do not raise any questions regarding its safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the eMotion ECG Mobile is substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, sterilization, biocompatibility, performance characteristics, and intended use.

The eMotion ECG Mobile, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

November 26, 2013

Mega Electronics Ltd.
c/o Mr. Andre Kindsvater
Senior Consultant QA/RA
Prinsessegracht 20
2514 AP, The Hague
Netherlands

Re: K131699
Trade/Device Name: Emotion ECG Mobile
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter & Receiver
Regulatory Class: II (two)
Product Code: DXH
Dated: October 22, 2013
Received: October 24, 2013

Dear Mr. Andre Kindsvater:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131699

Indications for Use Statement

510(k) Number (if known): _____

Device Name: eMotion ECG Mobile

Indications for Use:

The eMotion ECG sensor is a wearable, portable, externally applied, electrocardiograph recorder and transmitter for the purpose of health monitoring, biofeedback and scientific research.

The eMotion ECG Mobile is intended for use in clinical and non-clinical settings to collect and transmit health parameters to healthcare professionals for monitoring and evaluation. Health parameters are collected from a variety of commercially available, external plug-in devices such as ECG sensors, Weight Scales, Blood Pressure Meters and Pulse Oximeters.

The eMotion ECG Mobile does not provide any automatic analysis or diagnosis.

Prescription Use	AND/OR	Over-The-Counter Use _____
X _____		(21 CFR 801 Subpart C)
(Part 21 CFR 801 Subpart D)		

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.11.26 13:18:19 -05'00'